DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

m2399n RB 2/25/99

Certified/Return Receipt Requested

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

February 23, 1999

WARNING LETTER

Roger E. Jensen, President
Remel, Inc.
14000 Unity Street, NW
Ramsey, MN 55303-9115

KAN #99-014

Dear Mr. Jensen:

We are writing to you because on November 18 through December 7, 1998, an FDA Investigator from this office conducted an inspection of your facility located at 12076 Santa Fe, Lenexa, Kansas, which revealed a serious regulatory problem involving your in-vitro diagnostic products.

Under the Federal Food, Drug, and Cosmetic Act (Act), in-vitro diagnostic products are considered to be medical devices. The law requires that manufacturers of medical devices adhere to the Quality System Regulations. This helps protect the public health by ensuring that medical devices are safe and effective.

In legal terms, your devices are adulterated under the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformity with the applicable requirements under 21 U.S.C. 360(j)(l) and the Quality System Regulation, promulgated thereunder in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

- Failure to have a written corrective and preventative action procedure.
- Failure to have in place systems for analyzing recalls, complaints, internal device investigations, and other product quality programs.
- Failure to adequately investigate complaints to determine the problem source as evidenced by the following examples:
    - 21 complaints of fungus contamination on plates of SXT Blood Agar, Lot. No. 5697.

- 6 complaints of liquified media regarding Chocolate Agar, Lot No. 5715.
- 4 complaints of mold contamination in SXT Blood Agar, Lot No. 5694.
- 49 complaints of hemolyzed Blood Agar, Lot No. 6129.
- 49 complaints of hemolyzed Blood Agar, Lot No. 6134.

- Inadequate investigation of Medical Device Reporting (MDR) incident No. 1924669-1998-001 (skin laceration from broken tube of media).
- Failure to validate lyophilizer cycle parameters for specific moisture content; to test for moisture content during finished product release; and to have lyophilized product specifications established for moisture content.
- Failure to perform adequate lyophilizer validation studies.
- Failure to perform an adequate validation of the blood collection process.
- Failure to have a written procedure describing the decision process for changes to processes and Device Master Records.
- Failure to establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation. For example, there is no written procedure which describes the decision process on whether a design change may require only verification as opposed to validation.

This letter is not intended to be an all-inclusive list of deficiencies at this facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. At the conclusion of the inspection Form FDA 483 was issued to, and discussed with you. This is a list of the QSR deviations made by the Investigator during the inspection. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the Form FDA 483 may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the cause of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

A response letter from Mr. Donald R. Rousseau, Director of Quality Systems, of December 16, 1998, to the Form FDA 483 issued at the close of the current inspection was received and reviewed prior to the issuance of this letter.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of your product, or assessing civil money penalties. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking, in additon to the December 16 letter, to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Clarence R. Pendleton, Compliance Officer, at the above address.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter only pertains to the issue of Quality System Regulations, and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at http://www.fda.gov.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District

cc: Frank H. Jellinek, President
Sybron Laboratory Products Corp.
48 Congress
Portsmouth, NH 03801

CRP:tlw